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10/763,111	01/21/2004	William J. Wechter	3829.03-1	5923

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EXAMINER

ZHANG, NANCY L

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/763,111

Applicant(s)

WECHTER ET AL.

Examiner

Nancy L. Zhang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,8-10,12,13 and 18-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,11 and 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3 sheets.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Applicant's election of Group II, claims 1-24, in the reply filed on September 5, 2006, is acknowledged. Applicant's election of species (II-c) where the metabolic blocker is  $-C(X)D-$ , A is alkyl of 18 carbons, X is methyl and D is hydrogen, is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-48 are pending.

Claims 25-48 are withdrawn from consideration because they are directed to the non-elected invention.

Claims 3-4, 8-10, 12-13 and 18-24 are withdrawn from consideration because they are not directed to the elected species.

Claims 1-2, 5-7, 11 and 14-17 are examined.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the compound" in claim 1. There is insufficient antecedent basis for this limitation in the claim because "the compound" in claim 1 has

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already been defined as being a fatty acid. It is unclear what the recitation in claim 14 is intend to limit.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5-7, 11 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-2, 5-7, 11 and 14-17 are directed to a method of substituting a portion of the edible fat in a food composition with a compound that is a fatty acid including a physiologically acceptable ester thereof or a metabolic precursor thereof without any structural limitation. The specification only provides a statements that triglyceride esters of the fatty acid are particularly attractive as the fat substitute (page 36, lines 31-32) and provides as an example that R,R,S-phytol is a metabolic precursor of R,R,S-phytanic acid and subsequently R,R,S-pristanic acid as a result of metabolic oxidation and other processes (page 36, lines 12-14). The disclosure does not meet the written description provision of 35 USC § 112, 1st Paragraph. The specification provides insufficient

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written description to support the genus encompassed by claims 1-2, 5-7, 11 and 14-17 of a fatty acid including a physiologically acceptable ester thereof or a metabolic precursor thereof.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, whatever is not claimed.” (See page 1117). The specification does not “clearly allow persons of ordinary skilled in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116).

In the instant case, a skilled artisan cannot envision the detailed chemical structure of a physiologically acceptable ester in general of a fatty acid or a metabolic precursor of a fatty acid. Adequate written description requires more than a mere statement that it is part of the invention and reference to potential compounds. The chemical itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F. 2d 1008, 1012, 10 USPQ2D 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is

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claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d at 1572, 41 USPQ2D at 1966.

Therefore, claims 1-2, 5-7, 11 and 14-17 do not meet the written description provision of 35 USC § 112, 1st Paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision (see page 1115).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-7, 11 and 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Whyte (US Patent 3,579,548, issue date: May 18, 1971).

Claims 1-2, 5-7, 11 and 14-17 recite a method of reducing metabolic caloric content of a food composition comprising substituting edible fat of the food composition with a compound of a fatty acid or a physiologically acceptable ester thereof or a metabolic precursor thereof. The compound has the following structure:

**A – (metabolic blocker) – CO<sub>2</sub>H**

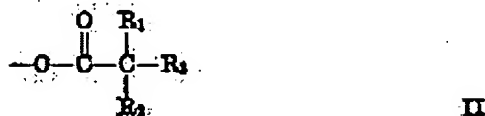
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where A is an alkyl of 18 carbon, the metabolic blocker is  $-\text{C}(\text{X})(\text{D})-$ , where X is methyl and D is hydrogen.

Whyte discloses triglyceride esters of  $\alpha$ -branched carboxylic acids that can be used as a partial or total replacement for ordinary triglyceride fat in fat-containing food composition to reduce the caloric value (column 2, lines 18-21). The low calorie fat compound has the general formula (I) defined as:



wherein X is an  $\alpha$ -branched carboxylic acid residue having the Formula II

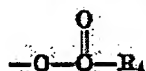


wherein

$\text{R}_1$  and  $\text{R}_2$  are each selected from alkyl groups of from 1 to 30 carbon atoms, and

$\text{R}_3$  is selected from hydrogen, and alkyl groups of from 1 to 30 carbon atoms, the total carbon atoms in  $\text{R}_1 + \text{R}_2 + \text{R}_3$  being from 8 to 30; and

Y and Z are each selected from X,  $-\text{OH}$ , and



wherein  $\text{R}_4$  is selected from alkyl, and alkene groups of 8 to 30 carbon atoms.

When  $\text{R}_1$  is an alkyl of 18 carbon,  $\text{R}_2$  is a methyl and  $\text{R}_3$  is hydrogen, the resulting compound as disclosed by Whyte is a physiologically acceptable ester of a compound that is identical to the compound of the instant application.

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Clearly, a method of reducing metabolic caloric content of a food composition by substituting edible fat of the food composition with a compound of a fatty acid or a physiologically acceptable ester thereof or a metabolic precursor thereof is anticipated.

Claim 14 recites the limitation where the composition comprises about 1% to about 100% of the edible fat. Whyte teaches a food composition wherein from about 10% to about 100% of the total fat comprises the glycerol esters of the  $\alpha$ -branched carboxylic acids (column 2, lines 50-53).

Claim 15 recites the limitation where the food composition comprises a protein or a carbohydrate or both. Whyte teaches that the low calorie fats can be used in food products such as mayonnaise, margarine and dairy products (column 7, lines 20-23).

The recitation of "having yield energy from beta-oxidation that is low enough to render said fatty acid metabolically low caloric" in the claims 1-2, 5-7, 11 and 14-17 and the recitation of "substantially incapable of beta-oxidation" in claim 16 are merely scientific explanation or function of the composition.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which



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there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Therefore, claims 1-2, 5-7, 11 and 14-17 are clearly anticipated.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*nlm 10/26/06*

NLZ

*Ardin H. Marschel 10/29/06*

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SUPERVISORY PATENT EXAMINER